

K063298



510(k) Summary

MAR 02 2007

Device Proprietary Name: OsteoMed Headless Cannulated Screw System

Device Common Name: Bone Screw

Classification Name: HWC, Screw, Fixation, Bone

Name of Submitter: OsteoMed L. P.
3885 Arapaho Road
Addison, Texas 75001
Phone: (972) 677-4600
Fax: (972) 677-4601

Contact Person: Dawn D. Tindall

Date Prepared: October 31, 2006

Summary:

This submission describes the OsteoMed Headless Cannulated Screw System indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation of bones appropriate for the size of the device. Screws are intended for single use only.

The OsteoMed Headless Cannulated Screw system is comprised of screws in diameters of 2.0mm (10-42mm length), 2.4mm (10-50mm length), 3.0mm (10-40mm length), 4.0mm (12-52mm length) and 6.5mm (40-120mm length). The screws are made of Titanium Alloy (ASTM F-136). Guide Wires, drills, taps, drivers, handle, depth gauge, bone clamp, screw extractor and preparation instruments will also be a part of the system.

Equivalence for this device is based on similarities in intended use, material, design and operational principle to the Nexa Compression Pin cleared under K060071, the Wright Multi Use Compression Screw (K043102), the Zimmer Herbert Bone Screw (K792022), the Vilex/Duval/Orthex Cannulated Bone Screw (K014154) and the OsteoMed Super Screw System (K954330).

Due to the similarity of materials and design to both pre-enactment and post-enactment devices, OsteoMed believes that the OsteoMed Headless Cannulated Screw System does not raise any new safety or effectiveness issues.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OsteoMed L.P.
% Ms. Dawn D. Tindall
3885 Arapaho Road
Addison, Texas 75001

MAR 02 2007

Re: K063298
Trade/Device Name: OsteoMed Headless Cannulated Screw System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener.
Regulatory Class: II
Product Code: HWC
Dated: February 5, 2007
Received: February 6, 2007

Dear Ms. Tindall:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

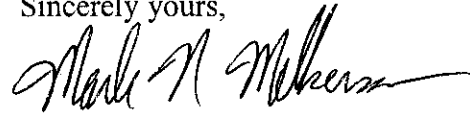
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", with a long horizontal flourish extending to the right.

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K063298/S001

Device Name: OsteoMed Headless Cannulated Screw System

Indications for Use:

The Osteomed Headless Cannulated Screw System is indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation of bones appropriate for the size of the device. Screws are intended for single use only.

Prescription Use ☒
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ☐
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Posted November 13, 2003)



(Division Sign-Off)

Division of General, Restorative,
and Neurological Devices

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